BiliChek®

Non-Invasive Bilirubin Analyzer

RESPIRONICS®
www.respironics.com

Children's Medical Ventures
RESPIRONICS®

Service Manual

This BiliChek system is the subject of U. S. Patent #US patent 5.353.790 5,792,049 5,860,421 5,924,981 6.002.482 6,045,502 6,192,734 and patents pending. BiliChek is a trademark of Respironics, Inc.

Limited Warranty

Respironics warrants that the Bili*Chek*® device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one year from the date of sale by Respironics. If the product fails to perform in accordance with the product specifications, Respironics will repair or replace -at its option - the defective material or part. Respironics will pay customary freight charges from Respironics to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse alteration, and other defects not related to materials or workmanship.

Respironics disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential dames, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition, any implied warranty, including any warranty of merchantability or fitness for the particular purpose, is limited to years. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

The warranty for repairs is ninety days for labor and one year on the part(s) that was replaced.

To exercise your rights under this warranty, contact Respironics Inc. at 1-800-345-6443 (US and Canada only) or 1-724-387-4000.

Visit Respironics Home Page on the World Wide Web: www.respironics.com

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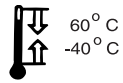
1.0 Symbols

- Symbol for “Attention. See Instructions For Use“
- Symbol for “Use With”
- Symbol for “Do Not Reuse”
- Symbol for “Use By”
- Symbol for “Batch Code”

- Symbol for “Recycle”
- Symbol for “Serial Number”

- Symbol for “Catalog Number”

- Symbol for “Storage Conditions” 

- Symbol for “Battery Deep Discharge and Recharge”
- Symbol for “battery Charging”
- Symbol for “Rechargeable Battery Recycle Corporation”

- Symbol for “Do Not Throw in Trash”
- Symbol for “Nickel Cadmium Battery”

- Symbol for “Indoor Use”
- Symbol for “Class B”
- Symbol for “Date of Manufacture” *Mfd:*
- Denotes this system is ETL Listed and conforms to ANSI/UL STD. 2601. Certified to CAN/CSA C22.2 STD. NO. 601.1.

2.0 Purpose of the Device

The Bili*Chek*®Non-Invasive Bilirubin Analyzer accurately determines bilirubin levels in newborn patients without a blood sample *regardless of their skin color, gestational age,* or *post-natal age.* This product provides *rapid, point-of-care* bilirubin measurements as a replacement for traditional clinical chemistry methods. These results are achieved with *no trauma to the patient, no risk of infection*, and *potentially reduced cost of monitoring serum bilirubin* by minimizing the use of hospital personnel and supplies.

3.0 Theory of Operation

The Bili*Chek* works by directing white light into the skin of the newborn and measuring the intensity of the specific wavelengths which are returned. By knowing the spectral properties of the components within the skin, one can subtract out the interfering components and determine the concentration of bilirubin.

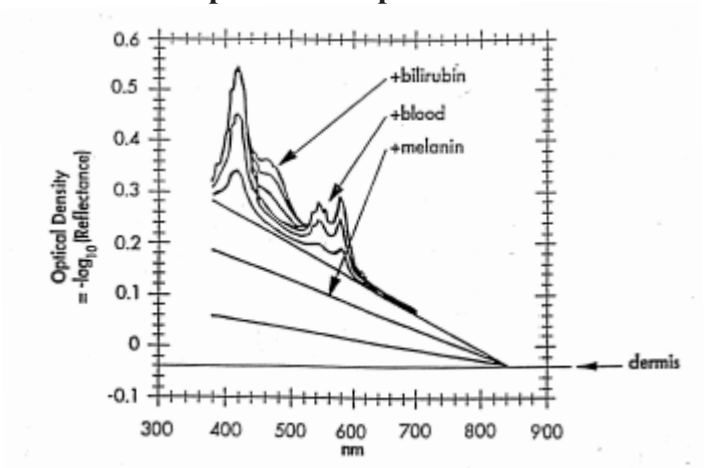
Each photon has a characteristic wavelength. As light enters skin tissue it can collide with the structural components such as collagen fibers. When a collision occurs, the photon loses energy and direction of travel is changed. This is called a scattering event. If enough of these scattering events occur, the photon completely loses its energy and is absorbed. If a photon is scattered such that it is re-emitted from the skin, it is reflected. Photons with longer wavelengths (in the red region of the spectrum) are scattered less than photons with shorter wavelengths (in the blue region of the spectrum). This phenomenon is called wavelength-dependent scattering and explains why the skin appears red when you shine a bright light through it. It is also one of the reasons why the optical properties of the newborn's skin changes with advancing gestational and post-natal age. As the skin matures, it becomes thicker and there is greater keratinization of the cell membranes which increases the scattering of incident light.

Photons of specific wavelengths are also preferentially absorbed by certain molecules. By plotting the absorption against the wavelength one can visualize characteristic absorption spectra of the particular molecules. For example, melanin has a near-linear absorption spectrum in the visible spectrum and, like the scattering phenomenon, there is greater absorption of photons with shorter wavelengths than in the red region of the spectrum. Conversely, hemoglobin is a much more complicated absorber which is compounded by the fact that oxyhemoglobin and deoxyhemoglobin have different profiles. The peak absorption of photons by bilirubin occurs at a wavelength of 460nm. This is in the blue portion of the spectrum and is the reason why blue lights are sometimes preferred for phototherapy. It is also in the region of the spectrum at which hemoglobin absorption is relatively low.

Theory of Operation (continued)

The light reflected from the skin of neonates and collected by the Bili*Chek* Non-Invasive Bilirubin Analyzer is analyzed with a highly sophisticated, proprietary algorithm to generate a serum bilirubin measurement. The major skin components which impact the spectral reflectance in newborns are (1) dermal maturity, (2) melanin, (3) hemoglobin, and (4) bilirubin. The intensity of the reflected light is converted to absorbance units, Optical Density (OD), for analysis. The total OD at each measured wavelength is equal to the sum of the component ODs. This is represented mathematically as: $\mathbf{OD}_{\mathbf{TOTAL}} = \mathbf{OD}_{\mathbf{DERM}} + \mathbf{OD}_{\mathbf{MEL}} + \mathbf{OD}_{\mathbf{HEME}} + \mathbf{OD}_{\mathbf{BILI}}$ By utilizing known spectral characteristics of each component, the contribution to the total OD can be sequentially subtracted until bilirubin is all that is remaining.

Non-Invasive Skin Spectral Components[1]



[1] Jacques, S., Saidi, I., Ladner, A., and D. Oelberg. Developing and optical fiber reflectance spectrometer to monitor bilirubinemia in meonates.

Each of these components have also been considered in the development of the algorithm by which the Bili*Chek* Non-Invasive Bilirubin Analyzer computes the bilirubin measurement. By measuring the intensity of the reflected light at more than 100 individual wavelength bands across the visible spectrum, a spectral analysis can be performed. By normalizing against a reference standard, the Bili*Cal*® Individual Calibration tip, the variations over time of the bulb and the photo-detectors are eliminated. The peak absorption of the bilirubin is at approximately 460nm as measured by subtracting the absorption of the other components from the total skin absorption. This is represented by the equation below.

$$\mathbf{OD}_{\mathbf{BILI}} = \mathbf{OD}_{\mathbf{TOTAL}} - \mathbf{OD}_{\mathbf{MEL}} - \mathbf{OD}_{\mathbf{HEME}} - \mathbf{OD}_{\mathbf{DERM}}$$

The absorption of light by a molecule is proportional to its concentration. Therefore, the absorption of bilirubin, as calculated above, is proportional to the concentration of bilirubin in the subcutaneous capillary beds and subcutaneous tissue. By subtracting the contribution of the aforementioned components, the bilirubin absorbance can be quantified and is correlated to the laboratory total serum bilirubin levels.

4.0 Warnings and Cautions

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

Warnings

- The Bili*Chek* Hand-Held Unit is to be operated only in conjunction with Respironics approved charger base, battery packs, power supply, and Bili*Cal*™ Individual Calibration Tips.
- Do not point at eyes while taking a measurement.
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with nitrous oxide.
- Do not use in areas of the skin with visible brusing.
- If you suspect Bili*Chek* is interfering with other electronic devices or vice versa, try the following measures to correct it:
  - Relocate the device until the interference stops.
  - Move the Bili*Chek* further away from the device.
  - Plug the Bili*Chek* power supply into a different power outlet so that the Bili*Chek* power supply and the device are on different breaker or fuse circuits.
- Do not puncture or incinerate the battery pack or dispose of in a landfill. Batteries should be disposed of properly according to local guidelines.
- Do not use outdoors or place in direct sunlight.
- The charger base unit (battery charger) should be plugged into a properly grounded outlet. Do not operate with damaged plug or cord.

Cautions

- The Bili*Cal* Individual Calibration Tip should not be exposed to light for extended periods of time. Keep Bili*Cal* Tip in package prior to use.
- If the product is dropped and frequent error messages occur, it should be inspected for proper operation by an authorized service representative.
- Do not immerse in water or other liquid.
- Do not let power cord hang over edge of counter or table as this may pose a tripping hazard.

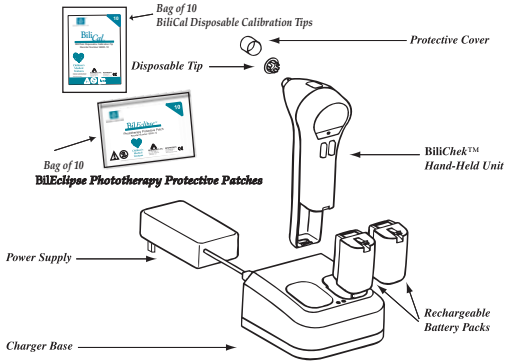
Contraindications

- Avoid using measurement sites when the following conditions since they can produce erroneous results:
  - Brusing
  - Birthmarks
  - Hematomas
  - Excessive hairiness
- The Bili*Chek* should not be used on patients who have undergone an exchange transfusion.

5.0 Description of the Bili*Chek*® System

The Bili*Chek* System (REF B809 or B801) consists of a hand-held unit (REF B800-13) and the following items:

Quantity	Description	REF Number
2	Rechargeable Battery Packs	B800-20
1	Charger Base	B800-21
1	Power Supply (International)	B800-17
1	Power Supply (Domestic)	B800-16
1	Table Top Power Supply (100/250V) 47/63Hz (optional)	B800-18
1	Bag of 10 Disposable Calibration Tips	B800-10
1	Bag of 10 BilEclipse Phototherapy Protective Patch	B800-12
1	User Instruction Manual	B800-19
1	Bili*Chek* Manual, International 1	B800-23
1	Bili*Chek* Manual, International 2	B800-24



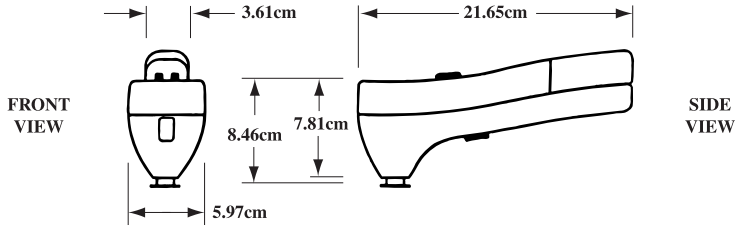
6.0 System Specifications

Bili*Chek* System:

- Total Weight 974g

Bili*Chek* Hand-Held Unit:

- Weight (with battery pack) 346g
- Dimensions ..... See figure below



Battery Packs:

- Type ..... Ni-Cd
- Dimensions
  - Height 6.5cm
  - Depth 4.8cm
  - Width 3.5cm
  - Weight 147g
- Voltage 6V
- Capacity ..... 700mA Hrs
- Measurements per full charge ..... Minimum 100 on a single charge
- Life Span ..... Minimum 1 year
- Recharge Cycle ..... 4.6 hours maximum
- Discharge and Recharge Cycle ..... 9.2 hours maximum

Charger Base:

- Dimensions
  - Height 7.6cm
  - Depth 12.1cm
  - Width 12.4cm
- Weight 264g

Light Bulb:

- Type ..... Tungsten
- Bulb Life ..... Minimum measurements

Power Supply:

Domestic

- Input 120V, 60Hz
- Output ..... 12 VDC, 0.75 Amp

International

- Input ..... 100-240 VAC ± 10% 47-63 Hz
- Output ..... 12 VDC, 2.75 Amp

Environmental Conditions for Use:

Bili*Chek* System and Bili*Cal* Individual Calibration Tip may be stored at -40°C to 60°C (-40°F to 140°F) with noncondensing relative humidity of 95% for a duration of at least 24 hours.

Bili*Chek* System and BiliCal Individual Calibration Tip are intended to operate between temperatures of 5°C to 40°C (41°F to 104°F) with 0% to 85% relative humidity without condensation.

7.0 Functional Description

Bili*Chek* Hand-Held Unit (HHU):

The Bili*Chek* Hand-Held Unit consists of the following functional components:

1. TRIGGER button - The single button on the bottom of the unit is called TRIGGER. It is used to initiate calibration and patient measurement.

2. FUNCTION buttons - The two buttons on the top side are FUNCTION buttons. The teal button on the left is referred to as F1, and the gray button on the right as F2. These are used to initiate non-routine functions such as set-up, changing time and date etc.

3. Bili*Cal* Individual Calibration Tip - This tip serves five purposes:
   a. device calibration before each patient measurement.
   b. protection of the fiber-optic probe,
   c. protection of the surface of the calibration material,
   d. positioning aid to ensure proper placement of the probe.
   e. a clean surface for each patient measurement.

4. Display window - The display window shows the bilirubin measurement, time and date, audio and battery icons, Measurement Status Indicator (MSI) as well as other system and error messages.

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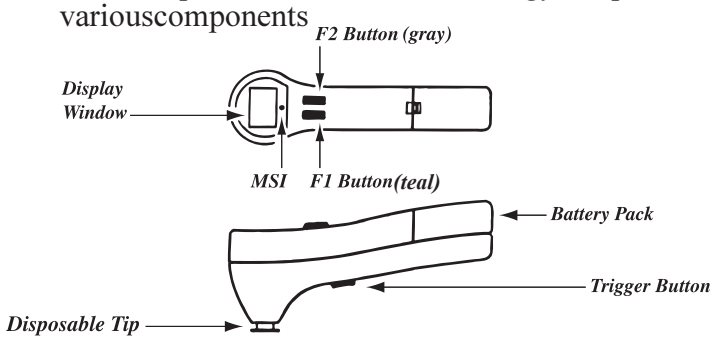
5. Battery Pack - Located in the bottom portion of the handle,it provides the electrical energy to operate the variouscomponents



Charger Base:

The charge base contains two wells, A and B, which recharge the battery pack in the Bili*Chek* HHU and a spare battery pack, respectively. The two small lights on the front of the charger base (Battery Status Indicators or BSI) indicate the operation of the battery charger and battery charge status.

- The Bili*Chek* HHU is placed in the left hand well "A" with the display window facing the operator.

- The spare battery pack is placed in the right hand well "B" with the latch up and facing the operator.

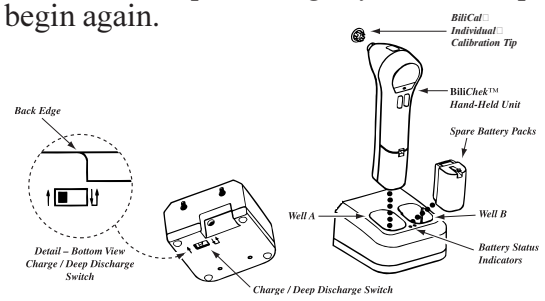
Caution: The Bili*Chek* Hand-Held unit will not fit in well "B" of the charger base. The battery pack can fit into well "A", but may not make correct connection to the charger base.

In order to maintain optimal battery performance and battery life, the battery packs should periodically be fully drained of power. The charger base has the ability to manually drain the battery by using the "Charge/Deep Discharge" switch located on the bottom of the charger base. It is recommended by the manufacturer to discharge each battery pack every month. To drain a battery pack of power, place the Deep Discharge switch in the "right" ( ) position and place the battery pack in the charger base. The discharge/recharge cycle will take approximately 4.6 to 9.2 hours depending on the amount of the charge in the battery pack.

The green light will illuminate when the battery pack has completely discharged and recharged. After both battery packs have been discharged, place the Deep Discharge switch in the "left" ( ) position.

Caution: Leaving the Deep Discharge switch in the "right" ( ) position at all times will drain the battery pack before **every** recharge. This will increase the duration of the recharging cycle and may reduce the overall life of the battery packs.

NOTE: If the battery pack is moved or bumped during the recharge phase of the deep discharge cycle, the deep discharge cycle may begin again.



The Battery Status Indicator (BSI)

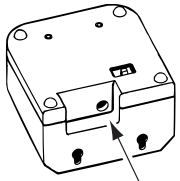
BSI Color	Battery Charger Mode	Solutions
OFF	Battery pack not sensed in well or charger base not properly connected to power supply.	Ensure battery pack is properly seated in well, check power connections. Try another battery if BSI is still off. If BSI is still off with second battery, the Charger base itself has malfunctioned and requires service.
Green	Battery pack is fully charged.	Battery pack is ready for use.
Amber	Battery pack in the well is charging but not ready for use.	Continue charging until BSI color is green.
Amber Flashing	Battery pack in the well is deep discharging.	Continue discharging and recharging until BSI color is green. **NOTE:** BSI will become steady amber when deep discharge phase of cycle is ended and charging is in progress.
Red Flashing	Bad battery pack in the charger base.	Replace the battery pack. If the problem is still present with a new battery pack, the charger base itself has malfunctioned and requires service.

NOTE: When Deep Discharging the battery pack, the BSI will **blink** amber during the discharge cycle, become **constant** amber when recharging, and then green when fully charge.

NOTE: IF the BSI is flashing red when the battery pack is in place, try resetting the battery pack in the charging well. If the problem persists, try another battery pack. If the problem continues, the charger base has malfunctioned and needs service.

8.0 Initial Set-Up

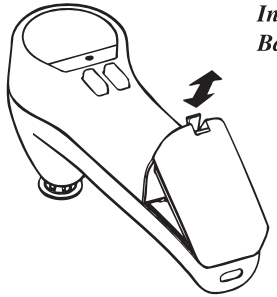
- Visually inspect that all components are without physical damage.
- Plug the power cord into the power supply and then into a grounded outlet.
- Connect the power supply to the charger base by inserting the plug into the socket on the rear of the charger base. The Battery Status Indicator (BSI) lights will flash red, green, amber, and then off (approxi mately 1 second each) to indicate proper operation.



REAR VIEW

Connect Power Supply to Charger Base Socket

- To install the battery pack, insert the bottom of the battery pack into the bottom of the Bili*Chek* hand held unit and then rotate battery and snap it into place.
- To remove the battery pack press the release latch at the top of the battery pack and rotate it out of the Bili*Chek* hand-held unit.



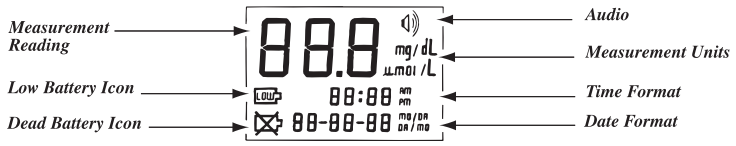
Install and Remove Battery Pack

Before the initial use, both battery packs should be fully charged. After installing one of the battery packs into the Bili*Chek* hand-held unit, insert the hand-held unit into the charger base well “A”, as shown on page 12 of this manual. The indicator light will glow amber to indicate that the battery pack is being charged (consult section 11.2 Troubleshooting Flow Chart of this manual if the indicator is blinking red or not illuminated). Now insert the auxiliary battery pack into well “B” as shown on page 12 of this manual. The BSI will glow amber to indicate that it is charging. Charge both battery packs fully until green lights are displayed on both BISs (page 12)

9.0 Set-Up Mode

To initially set up the Bili*Chek*® or to customize it for a specific institution, the following list of features can be changed from the initial factory settings.

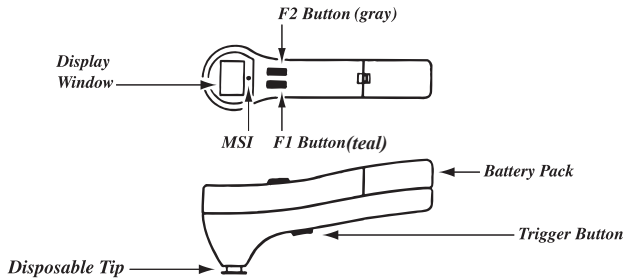
- Select audio On/Off
- Select the measurement units (mg/dl or µmol/L)
- Set the automatic power-off time interval (60 or 120 seconds)
- Select the time format (12H or 24H)
- Set the current time
- Select the date format (MO/DA or DA/MO)
- Set the current date



To Turn The Unit On

- Install a fully charged battery pack. Ensure that the battery pack is fully in place and latched. If EOO is displayed, see Section 11.0 of this manual.
- Press and release either F1 or F2
- The unit will turn on and boot up the system. During this boot-up, the software checks the main software, activates the measurement light bulb, Measurement Status Indicator, and all LCD indicators. The current software revision and current configuration are dis played. The boot-up will end at the home screen dis playing the last measurement, time and date, or display an error code message.

NOTE: The Bili*Chek* hand-held unit does not have an OFF switch. The power will automatically shut off if it is left idle for a specified period of time (60 or 120 Seconds).

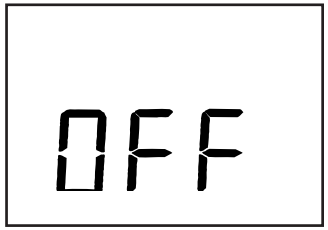


To Access the User Set-Up Function

- Press F1 and F2 at the same time, hold for one second, (until the display changes) and then release to access the set-up mode.
- Use the F1 button to advance to the next item and the F2 button to change the value of the current item.
- To exit the set-up mode, press F1 and F2 at the same time. All changes that were made will be saved and displayed.

Audio On/Off

- This function allows the user to turn the internal beeper on or off.
- Press F2 to toggle the speaker (beeper) on and off, and F1 to accept your choice and advance to the next function.



Setting the measurement units.

The display will read SET, and either mg/dL or µmol/L will be displayed

NOTE: The default value is mg/dL.

- Press F2 to toggle between values, and F1 to accept your choice and advance to the next function.

Automatic power-off time interval

To conserve battery power, the unit has an automatic time-out feature which turns the unit off if it is idle for a specified time period.

NOTE: The default time is set at 120 seconds.

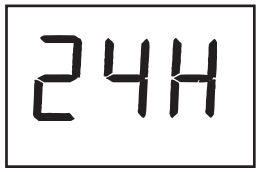
- Press F2 to toggle between the 60 or 120 second choices, and F1 to accept your choice and advance to the next function.

Selecting the time format

The system will display time in either the 12 hour or 24 hour format.

NOTE: The 12 hour format is the default setting.

- Press F2 to toggle between the formats, and F1 to accept your choice and advance to setting the time.



Setting the time

After choosing the time format SET appears on the display and the current clock time will be shown.

- The hour digits will be flashing
- Press F2 to scroll through the hours.
- Press F1 to accept the hour and the minute digits will begin flashing.
- Press F2 to scroll through the minutes.
- Press F1 to accept your choice and advance to the next function.

Selecting the date format

The unit will display the date in the Month/Day format or the Day/Month format.

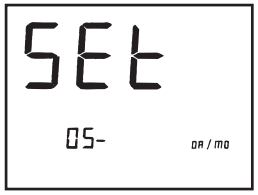
NOTE: the Month/Day format is the default setting.

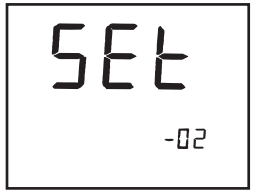
- Press F2 to toggle between the formats, and F1 to accept and to advance to setting the date.

Setting the date

Depending on the format selected, the current month or day digit will flash.

- Press F2 to scroll through the choices.
- Press F1 to accept and the next digit will begin flashing.
- Press F2 to scroll through the choices.
- Press F1 to accept, and the first year digit will begin flashing.
- Press F2 to scroll through the digits.
- Press F1 to accept and the second year digit will begin flashing.
- Press F2 to scroll the digits.
- Press F1 to accept and the date will be saved and the display will return to the home screen.





10.0 Operation Of The Device

10.1 Performing A Calibration

- Apply a new Bili*Cal* ™ Individual Calibration Tip to the unit.
- Firmly press the Bili*Cal* tip onto the Bili*Chek* hand-held unit to ensure proper seating of the Tip.
- Press and release either F1 or F2.
  The unit will perform its self test displaying all LCD indicators and end at the home screen
- Press and release the TRIGGER to start the calibration cycle.
- Three dashes (---) will flash in the display window and the MSI will be amber if a Bili*Cal* Tip is in place, indicating the system is ready to calibrate. If a Bili*Cal* Tip is not in place the MSI will be red, indicating that a new Bili*Cal* tip should be applied.
- Press and release the TRIGGER button. The dashed lines will stop flashing indicating that the unit is calibrating.
- When calibration is complete the MSI will be amber, you will hear a beep (if the audio is on), and the display window will read "005".

NOTE: If an error message is displayed during calibration, refer to section 11.0 of this manual for troubleshooting.

WARNING: It is critical to calibrate the unit and apply a new Bili*Cal* Individual Calibration Tip immediately prior to performing a test. Inaccurate test results will occur if this is not done. Removal of the tip after calibration and prior to a patient measurement will result in loss of calibration. The entire calibration sequence must be repeated with a new calibration tip.

10.2 Performing A Measurement

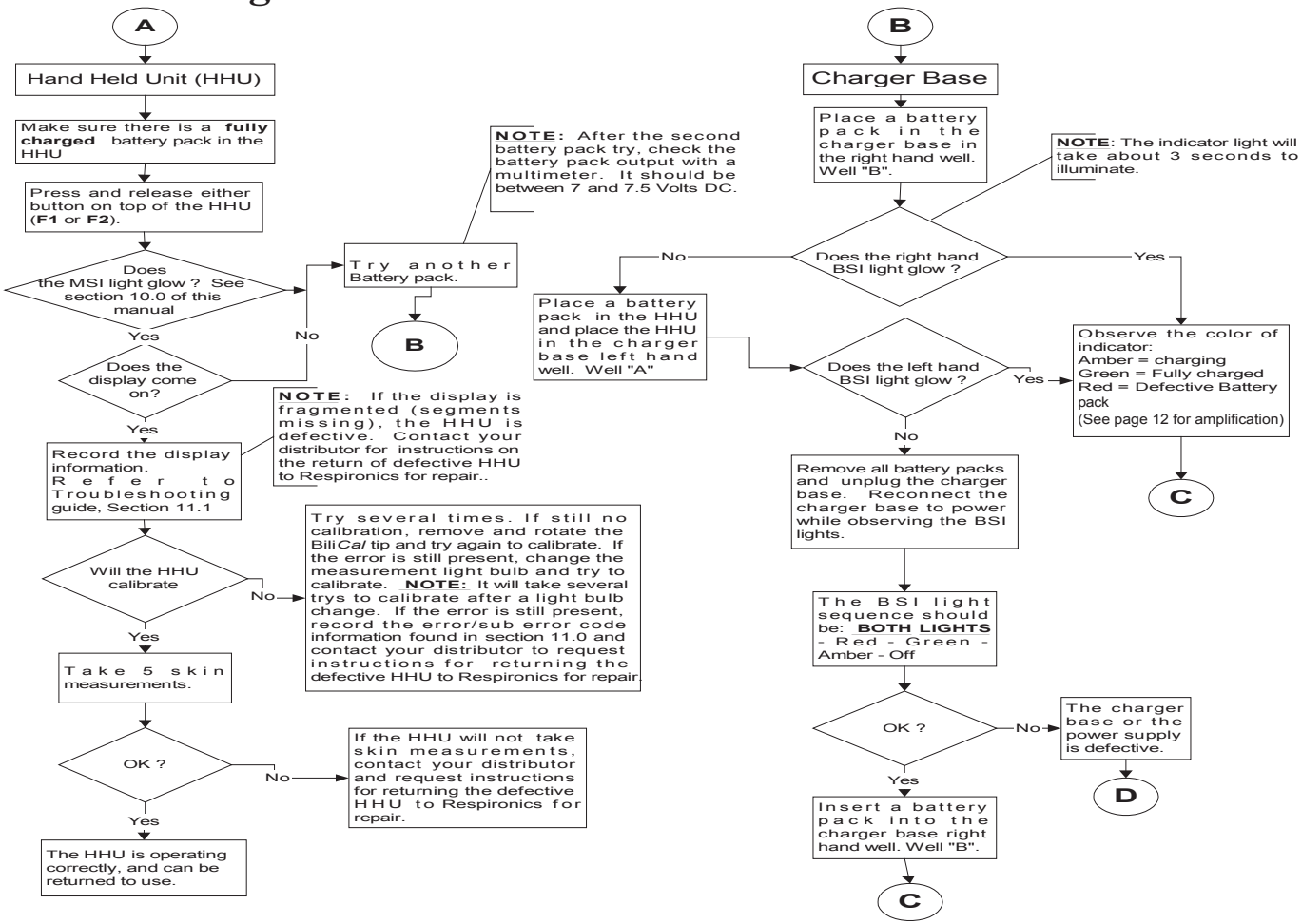
- After performing a calibration, peel the protective cover from the Bili*Cal* Individual Calibration Tip and dispose of it.
- Press and release the TRIGGER button. The unit is now activated and ready to take a measurement. Gently press the tip against the infant's forehead. The Measurement Status Indicator (MSI) will change from amber to green when proper pressure is applied. Do not continue to increase pressure, this will result in an E04 error message.
- The display will read "005" and will stop blinking when proper pressure has been applied. The measure ment should take less than 2 seconds. At the end of the measurement, a beep will sound (if audio is on) and the display will change to "004".
- Take "005" readings by lifting and replacing the tip on the forehead and pressing the TRIGGER button for each measurement. The current measurement will be indicated on the display (005-004-003-002-001)
- When the 5 measurements are complete, a beep will sound (if the audio is on) and the results will be dis played with the current date and time.
- Place the protective cover onto the BiliChek per manufacturer's recommendation. (If the protective cap is lost a BiliCal may be used to protect the fiberoptic probe.)
- The unit will turn off automatically.

11.0 Troubleshooting Guide

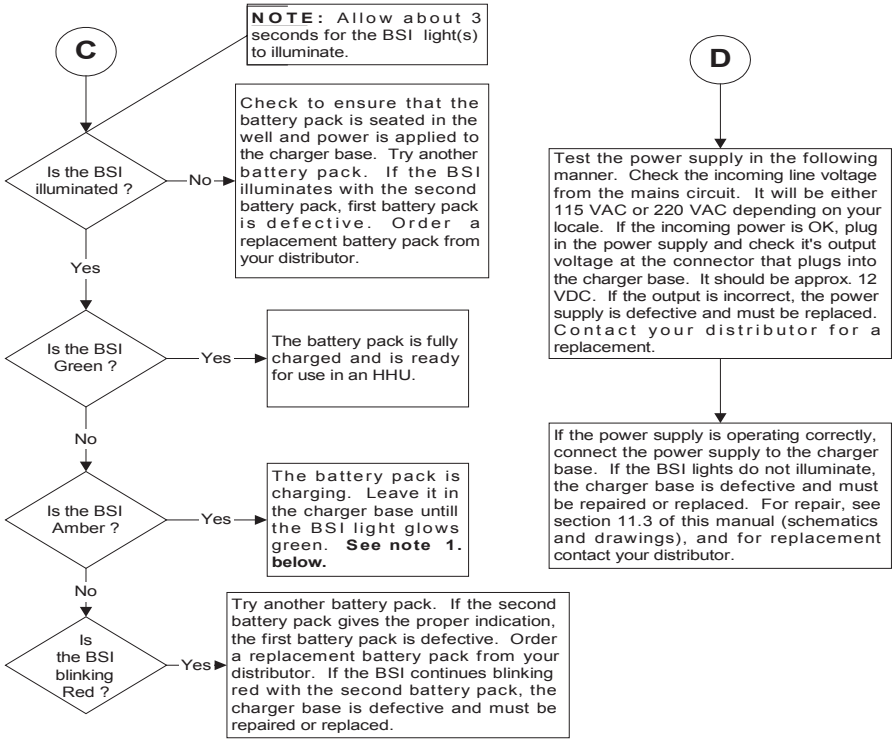
11.1 Troubleshooting Guide

Display Window	Indication	Solution
E00	No user set-up information identified.	Install a charged battery pack into the HHU. Press **F1** and **F2** at the same time, hold for one second and then release. This places the HHU in the Set-up mode. Enter settings specific to your institution. See section 10.0 of this manual for Set-up Mode instructions.
E01	Calibration measurement is unacceptable.	Press and release **F1** and **F2** at the same time. Ensure Bili*Cal* tip is in place and retry the calibration. If the error continues: 1. Place a **fully charged** Battery Pack in the HHU, install a new BiliCal Tip, and try again to calibrate several times. 2. Remove and rotate the Bili*Cal* tip and retry. 3. Replace the measurement light bulb (see Section 14.1 for instructions) and retry. If the error is still present, the HHU has malfunctioned and requires service. Call Respironics or your distributor.
E02	Patient measurement is unacceptable.	Press and release **F1** and **F2** at the same time. Take another measurement. If E02 occurs again, replace the Bili*Cal* tip, repeat calibration and retry the measurement. If the error is still present, the HHU has malfunctioned and requires service. Call Respironics or your distributor.
E03	Bili*Cal* Individual Calibration Tip removed between calibration and measurement scan.	Press and release **F1** and **F2** at the same time. Remove the Bili*Cal* Individual Calibration Tip. Replace with a new tip and recalibrate.
E04	Too much movement during measurement.	Press and release **F1** and **F2** at the same time. Perform another measurement.
E05	High Measurement is out of clinically proven range.	Obtain a Total Serum Bilirubin level (TSB)
E10	Light bulb is burned out.	Replace measurement light bulb (see section 14.1 for instructions). If error continues, the HHU has malfunctioned and requires service. Call Respironics or your distributor.
E99	System error is detected.	Call for Service.
	Low battery pack. Maximum of 10 measurements left.	Replace current battery pack with a fully charged battery pack from the charger base and place the discharged battery in well “B” for charging.
	Discharged Battery pack. No measurements can be taken.	Replace current battery pack with a fully charged one from the charger base. Place the discharged battery pack into well “B” for charging.

11.2 Troubleshooting Flow Chart


A
Hand Held Unit (HHU)
Make sure there is a fully charged battery pack in the HHU
Press and release either button on top of the HHU (F1 or F2).
Does the MSI light glow ? See section 10.0 of this manual
Yes
No
Try another Battery pack.
B
NOTE: After the second battery pack try, check the battery pack output with a multimeter. It should be between 7 and 7.5 Volts DC.
Does the display come on?
Yes
No
NOTE: If the display is fragmented (segments missing), the HHU is defective. Contact your distributor for instructions on the return of defective HHU to Respironics for repair..
Record the display information. Refer to Troubleshooting guide, Section 11.1
Will the HHU calibrate
No
Try several times. If still no calibration, remove and rotate the BiliCal tip and try again to calibrate. If the error is still present, change the measurement light bulb and try to calibrate. NOTE: It will take several trys to calibrate after a light bulb change. If the error is still present, record the error/sub error code information found in section 11.0 and contact your distributor to request instructions for returning the defective HHU to Respironics for repair.
Yes
Take 5 skin measurements.
OK ?
No
If the HHU will not take skin measurements, contact your distributor and request instructions for returning the defective HHU to Respironics for repair.
Yes
The HHU is operating correctly, and can be returned to use.
B
Charger Base
Place a battery pack in the charger base in the right hand well. Well "B".
NOTE: The indicator light will take about 3 seconds to illuminate.
Does the right hand BSI light glow ?
No
Yes
Place a battery pack in the HHU and place the HHU in the charger base left hand well. Well "A"
Does the left hand BSI light glow ?
Yes
No
Observe the color of indicator:
Amber = charging
Green = Fully charged
Red = Defective Battery pack
(See page 12 for amplification)
C
Remove all battery packs and unplug the charger base. Reconnect the charger base to power while observing the BSI lights.
The BSI light sequence should be: BOTH LIGHTS - Red - Green - Amber - Off
OK ?
No
The charger base or the power supply is defective.
D
Yes
Insert a battery pack into the charger base right hand well. Well "B".
C

Troubleshooting Flow Chart (continued)


C
NOTE: Allow about 3 seconds for the BSI light(s) to illuminate.
Is the BSI illuminated ?
No
Check to ensure that the battery pack is seated in the well and power is applied to the charger base. Try another battery pack. If the BSI illuminates with the second battery pack, first battery pack is defective. Order a replacement battery pack from your distributor.
Yes
Is the BSI Green ?
Yes
The battery pack is fully charged and is ready for use in an HHU.
No
Is the BSI Amber ?
Yes
The battery pack is charging. Leave it in the charger base untill the BSI light glows green. See note 1. below.
No
Is the BSI blinking Red ?
Yes
Try another battery pack. If the second battery pack gives the proper indication, the first battery pack is defective. Order a replacement battery pack from your distributor. If the BSI continues blinking red with the second battery pack, the charger base is defective and must be repaired or replaced.
D
Test the power supply in the following manner. Check the incoming line voltage from the mains circuit. It will be either 115 VAC or 220 VAC depending on your locale. If the incoming power is OK, plug in the power supply and check it's output voltage at the connector that plugs into the charger base. It should be approx. 12 VDC. If the output is incorrect, the power supply is defective and must be replaced. Contact your distributor for a replacement.
If the power supply is operating correctly, connect the power supply to the charger base. If the BSI lights do not illuminate, the charger base is defective and must be repaired or replaced. For repair, see section 11.3 of this manual (schematics and drawings), and for replacement contact your distributor.

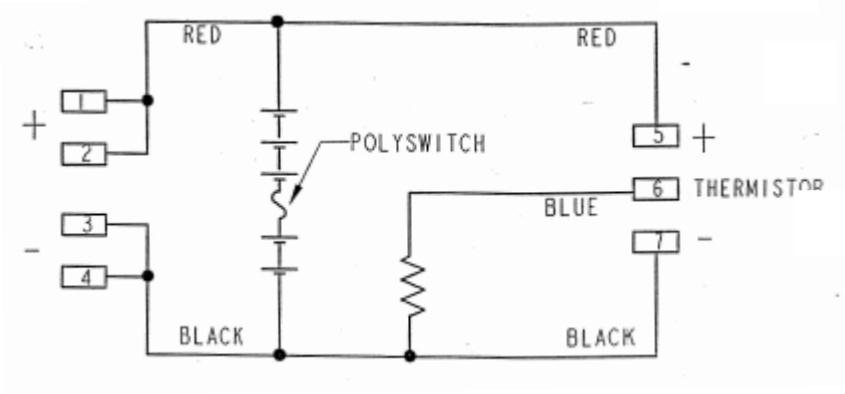
NOTES:

1. Ensure that the black switch located on the bottom of the charger base is in the left ( ) position (charge only). If the BSI is blinking amber, the charger is in the deep discharge/ recharge mode and the battery pack is discharging. The BSI will glow steady amber when the battery pack is charging, and green when the battery pack is fully charged.

2. Ensure that all contacts on both the battery pack and the charger base are clean, not bent over or broken off, and free of any obstructions.

11.3 Drawings and Schematics

11.3.1 Battery Pack Electrical Schematic



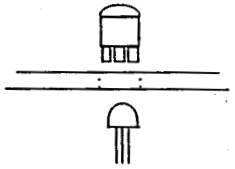
Votage Readings

Using a standard Digital Voltmeter, the following voltage readings will be obtained from a fully charged battery:

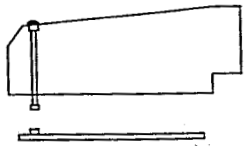
Pin 1 to Pin 4 = 7.0 VDC (± depending on polarity of leads)
Pin 5 to Pin 7 = 7.0 VDC (± depending on polarity of leads)
Pin 5 to Pin 6 = 7.0 VDC (± depending on polarity of leads)
Pin 6 to Pin 7 = 0.0 VDC

NOTE: The battery packs have three (3) contacts on one end and four (4) contacts on the other end. Holding the battery pack with the contacts towards you, the contacts are numbered from left-to-right.

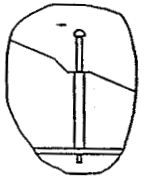
11.3.2 Charger Base Exploded Views



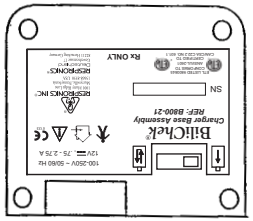
BSI LED and cover assembly



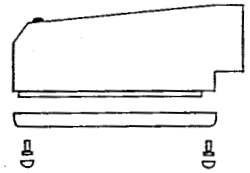
BSI LED and cover assembly



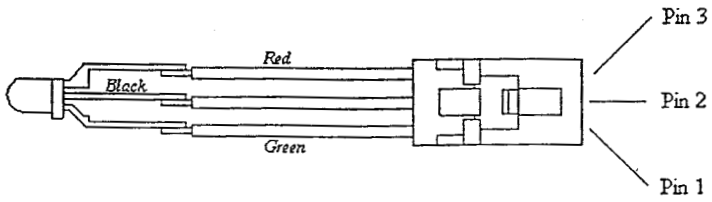
Cutaway view showing battery contact pin assembly



Bottom View of Charger base

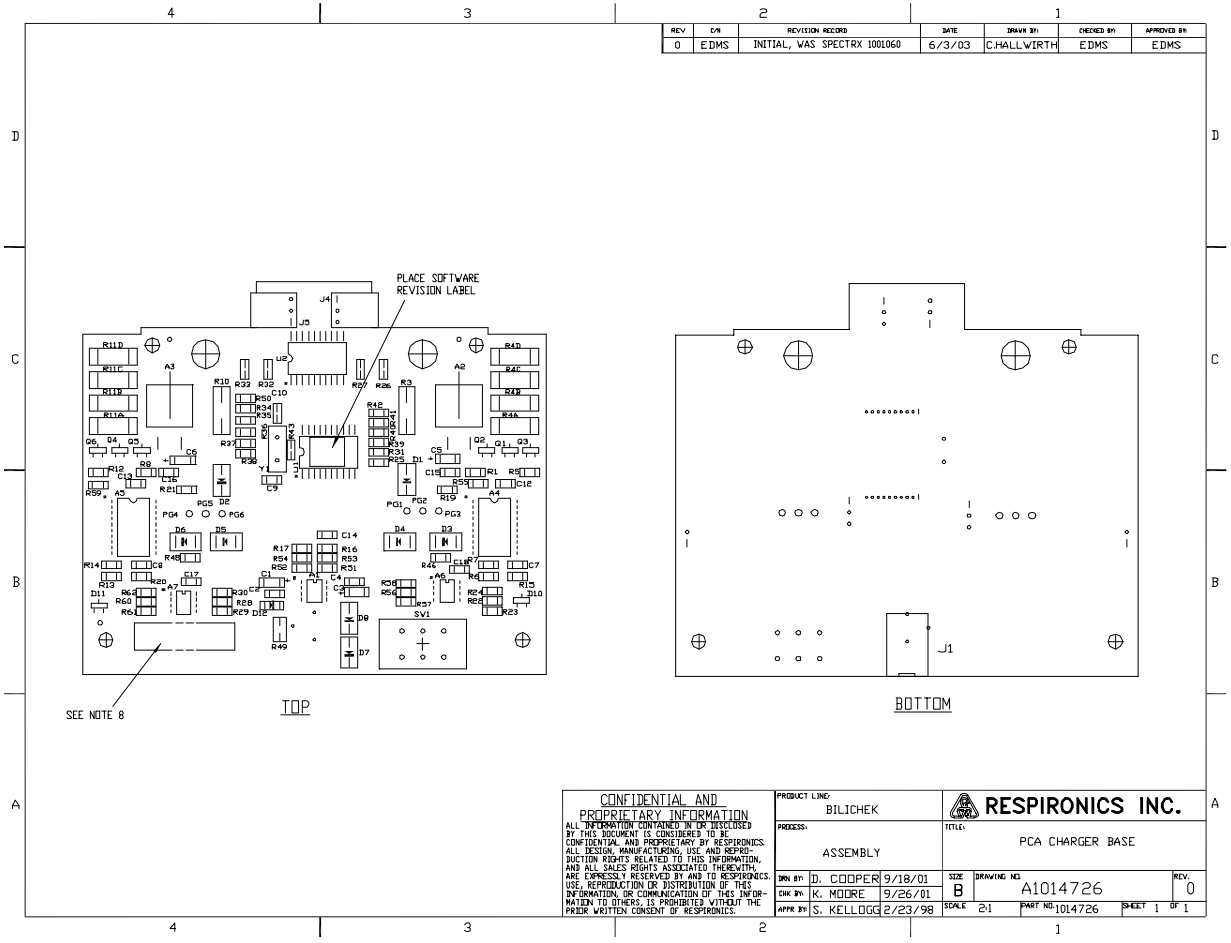


Exploded view of physical assembly top and bottom of charger base.



BSI LED harness assembly

11.3.3 Charger Base PCB Schematic


REV | D/N | REVISION RECORD | DATE | DRAWN BY: | CHECKED BY: | APPROVED BY:
0 | E.DMS | INITIAL, WAS SPECTRX 1001060 | 6/3/03 | C.HALLWIRTH | E.DMS | E.DMS
PLACE SOFTWARE REVISION LABEL
SEE NOTE 8
TOP
BOTTOM
J1
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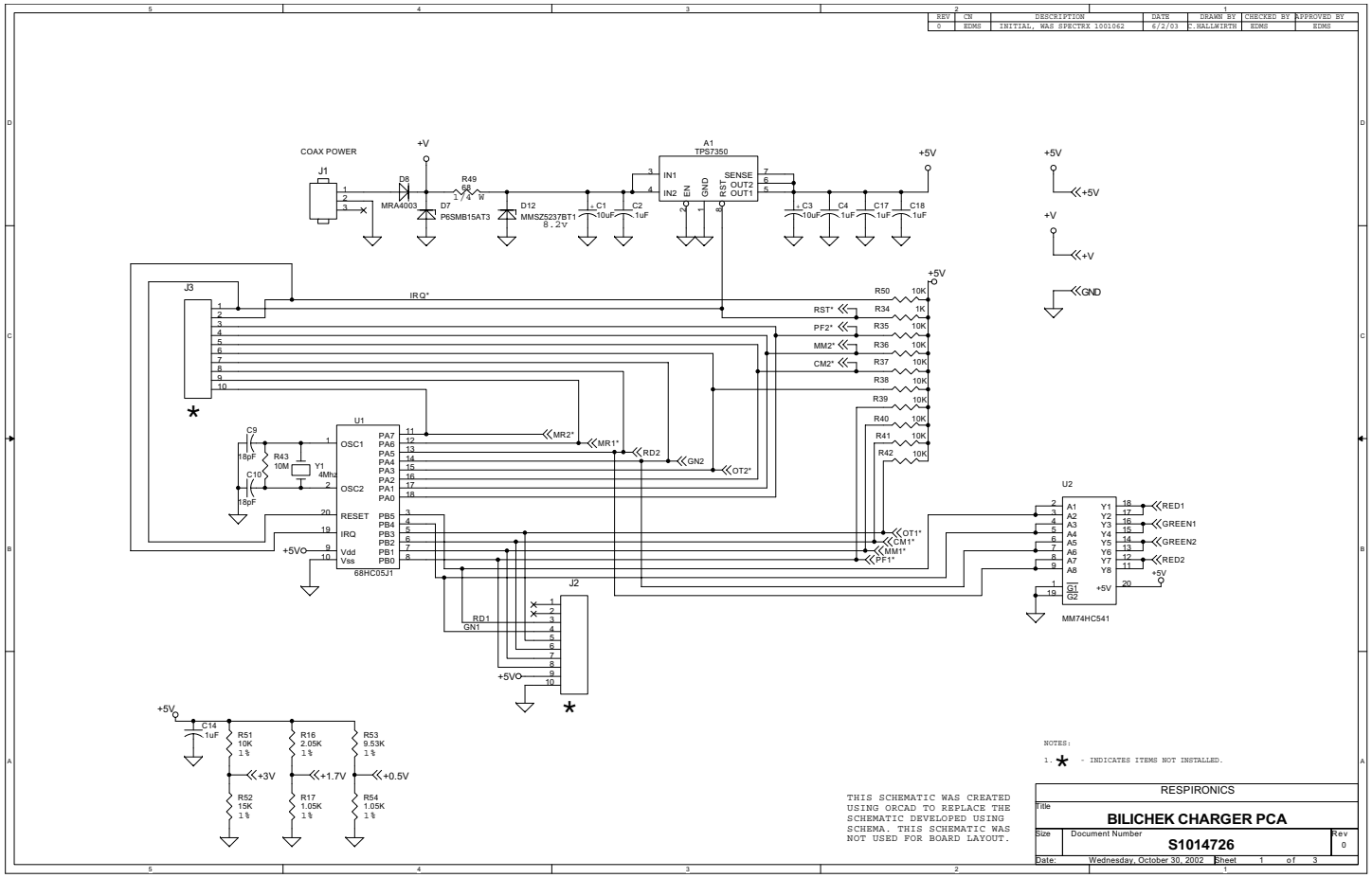
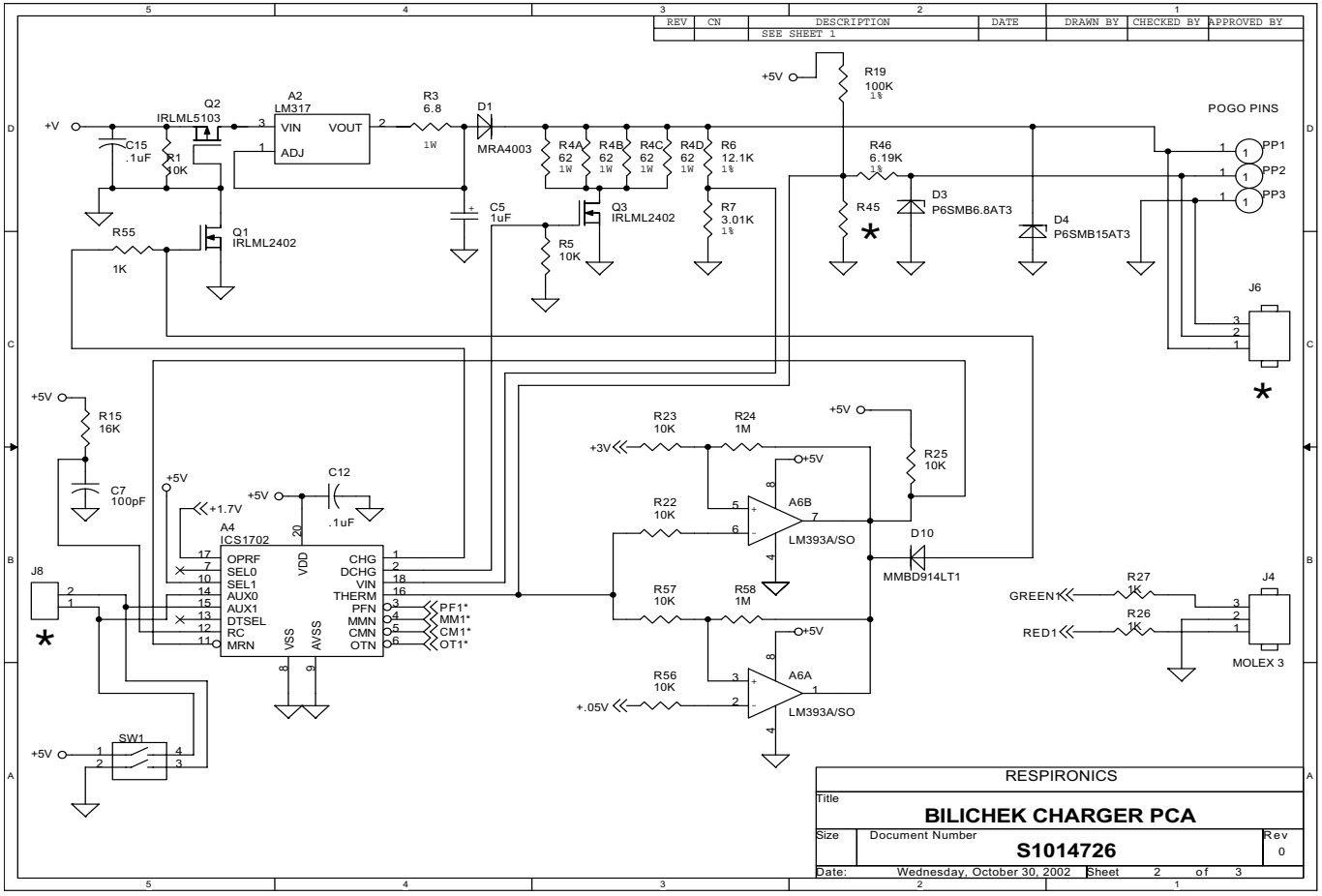
PRODUCT LINE: BILICHEK
PROCESS: ASSEMBLY
RESPIRONICS INC.
TITLE: PCA CHARGER BASE
DRN BY: D. COOPER 9/18/01
CHK BY: K. MOORE 9/26/01
APPR BY: S. KELLOGG 2/23/98
SIZE: B
DRAWING NO: A1014726
REV: 0
SCALE: 2:1
PART NO: 1014726
SHEET 1 OF 1

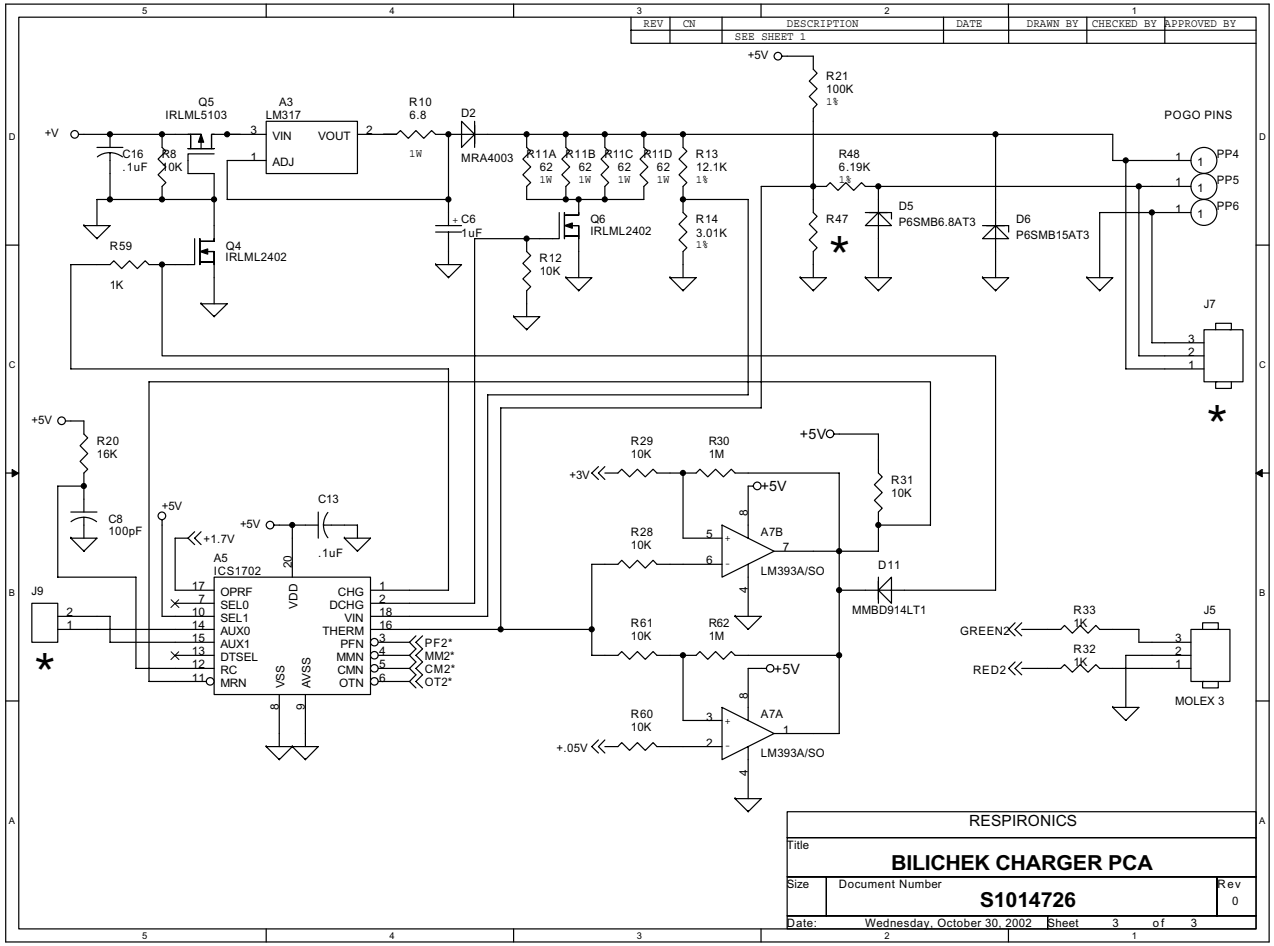
Charger Base PCB Schematic (continued)



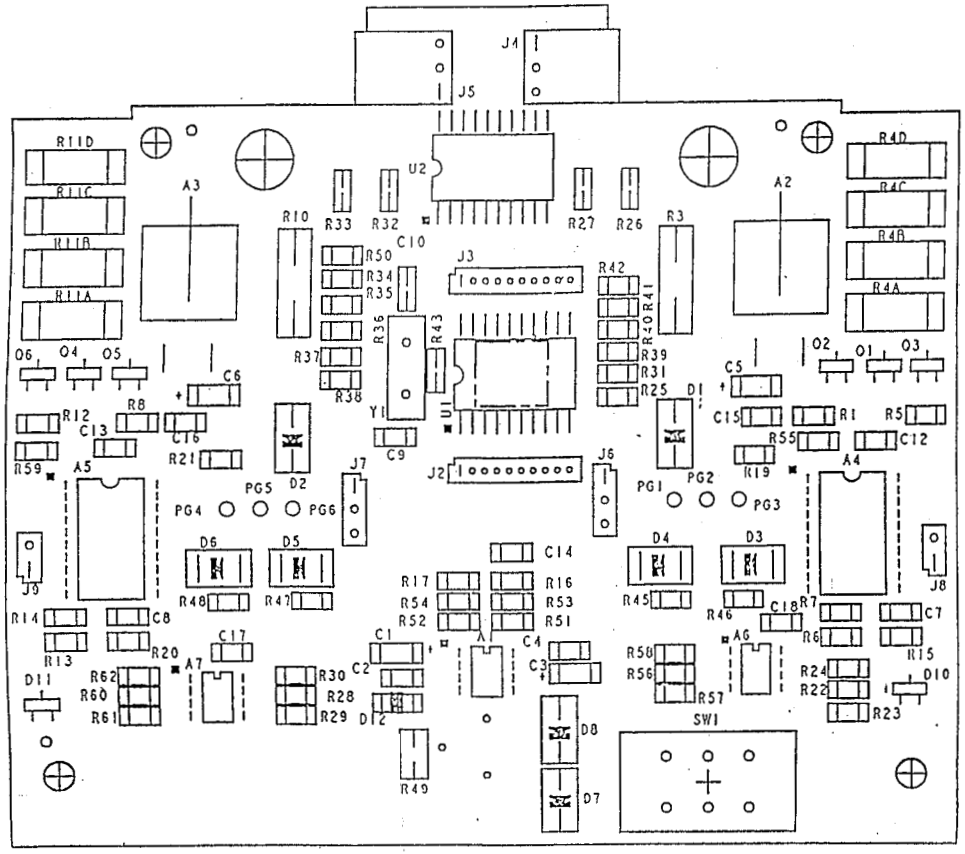
Charger Base PCB Schematic (continued)



Charger Base PCB Schematic (continued)



11.3.4 Charger Base PCB Component Layout



11.4 Hand Held Unit (HHU) Error Code List with Explainations

NOTE: All sub errors are displayed in the date field unless specified otherwise in each section. See Illustration at the top of page 32.

Error: E01	**Calibration**
Sub Errors	**Description**
000001	Reference component out of range. Install a fully charged battery pack and try several calibrations with new Bili*Cal* tips. If error persists, HHU requires service.
000002	Dynamic integration time out of range. Install a fully charged battery pack and try several calibrations with new Bili*Cal* tips. If error persists install a new measurement light bulb and try calibration several times. If the error still persists, the HHU requires service.
000004	Shape index above threshold. Try a fully charged battery pack and a new Bili*Cal* tip. If error persists, HHU requires service.
000008	Peak pixel not found. Install a fully charged battery pack and try several calibrations with new Bili*Cal* tips. If error persists, HHU requires service.
008192 NOTE: Firware Version ≥ 2.4/3.8 Only	Stray Light Slope Error. Install a fully charged battery pack and try several calibrations with new Bili*Cal* tips. If error persists, HHU requires service.
016384	Mean of dark scan data above threshold. Install a fully charged battery pack and try several calibrations with new Bili*Cal* tips. If error persists, HHU requires service.

Error: E02 - Measurement

Sub Errors	Description
000001	Light intensity below lower threshold specified in data configuration parameters. Try several calibrations and measurements. If error persists, try on another patient. If error persists on several patients, HHU requires service.
000002	Light intensity above upper threshold specified in data configuration parameters. Same as in 000001.
000008	Bili*Chek* bilirubin measurement below lower limit. Same as in 000001.
008192 NOTE: Firware Version ≥ 2.4/3.8 Only	Stray Light Slope Error. Try several calibrations and several Bili*Cal* tips. If error persists, HHU requires service.
016384	Mean of dark scan data above threshold. Try several calibrations and measurements. If error persists, HHU requires service.

Error: E03 - Disposable
Disposable tip removed after calibration and before measurements completed. Ensure tip is firmly attached an try another calibration and measurement. NOTE: This error can also occur if HHU is operated in sunlight or other bright light. Cover the IRDA port on the front of the HHU and perform another calibration and another measurement.

Error: E04 - Movement
Excessive movement detected during measurement. Take another measurement ensuring no movement of the Bili*Chek* hand-held unit while the MSI is green.

Error: E05 - Bili*Chek* Bilirubin Measurement High
Bili*Chek* Bilirubin measurement is above the upper threshold. The Bili*Chek* Non-Invasive Bilirubin Analyzer has an upper threshold of 20 mg/dl or 340 µmol/L set in the software. If readings are above this threshold, a blood sample must be taken to measure the TSB level.

HHU Error Code list with Explanations (continued)

Error: E10 - No Lamp Current
Measurement lamp burned out. Replace measurement lamp and perform several calibrations until HHU calibrates. If HHU will not calibrate after numerous tries, HHU requires service.

Error: E99 - Fatal
Fatal software error. The HHU must be returned for service. Contact your distributer to request instructions to return to Respironics for repair.
The following tables are for information only. If an E99 occurs, record the sub error and place a note with the HHU when returning it for service.

Error: E99 - Fatal (Sub Error Tables)

Sub Errors	Description
0001	System configuration parameters are not valid
0002	Timer could not be allocated
0004	Audio could not be initialized
0008	RTC could not be initialized
0016	Serial port could not be initialized
0032	LCD could not be initialized
0064	Switches could not be initialized
0128	Microspectrometer configuration data is not valid
0256	Internal reference voltage is out of range
0512	System RAM check failed
1024	Checksum error in boot firmware
2048	Checksum error in main firmware
4096	Firmware version in boot block not found
8912	Watchdog timer could not be initialized
16384	Watchdog timer timed-out

NOTE: The following sub errors are displayed in the date field.

Firmware version 2.3/3.6 and below

Sub Errors	Description
0256	External reference voltage outside of limits
0512	5V analog supply below limit
1024	Programming voltage below limit
2048	Clinical Error
4096	Internal system error detected during clinical testing
8192	Microspectrometer SN = 000000

Firmware version 2.4/3.8 and above

Sub Errors	Description
0016	Peak pixel range > 25
0032	External reference voltage outside of limits
0064	5V analog supply below limit
0128	Programming voltage below limit
0256	Clinical error
0512	Internal system error detected during clinical testing
1024	Microspectrometer SN = 000000

12.0 Routine (Operator) Cleaning

The Bili*Chek* System is made of an easy-to-clean material with a smooth, textured surface. One of the following cleaning agents is recommended for cleaning the exterior of the HHU, Battery Charger Base, and Battery Packs:

- KleenaSeptic®
- Cavicide®
- 70 to 90% Isopropyl Alcohol solution
- 1% Bleach solution

Spray the cleaning agent on a soft damp cloth and wipe clean the Bili*Chek* system. The same procedure can be used to clean the display window.

Caution: Clean the measurement tip with 90% or higher Isopropyl Alcohol using a soft optical surface cleaning wipe.

WARNING: Do not immerse any part of the system in water or other liquid. If liquids spill onto the unit, wipe with a damp cloth and allow to dry prior to using the system.

WARNING: Do not attempt to clean and/or reuse the Bili*Cal*™ Individual Calibration Tip.

13.0 Maintenance and Repair and Replacement

13.1 Hand Held Unit (HHU) Measurement Light Bulb Replacement

If the instrument bulb is not working and error code E01 or E10 (refer to the troubleshooting section 11.4) is displayed, it is necessary to replace the measurement light bulb. A Replacement Bulb Kit (RI P/N B800-22) is available from Respironics or your local distributor.

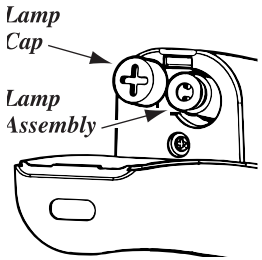
WARNING: The Bili*Chek*® Non-Invasive Bilirubin Analyzer is to be used only with the approved Replacement Bulb Kit from Respironics. Do not over-tighten the lamp cap.

- Remove the battery pack from the bottom of the HHU.
- Remove the protective label covering the lamp assembly.
- Remove the lamp cap using a flat tip screwdriver.
- Grab the loop of the light bulb with forceps or similar tool/instrument and gently pull to remove the lamp assembly.
- Insert the replacement lamp assembly using caution not to touch bulb with fingers. Be sure to place bulb into socket firmly. DO NOT use the lamp cap to tighten bulb into place.
- Apply the new lamp cap and protective label furnished in the kit.
- Insert a fully charged battery pack into the bottom of the HHU.

13.1 HHU Measurement Light Bulb Replacement (continued)

- Attach a new Bili*Cal*™ Individual Calibration Tip to the Bili*Chek* hand held unit.
- Turn the instrument on and perform repeated calibra tions as outlined in Section 10.1 of this manual, until a successful calibration is achieved.

WARNING: There are no serviceable components in the HHU. Removal of the junction screw and attempting to separate the upper and lower housings of the HHU can cause irreversible damage to the internal fiber-optics and will invalidate the manufacturers warranty.



13.2 Charger Base Repair and Replacement

The Bili*Chek* charger base is a micro-processor controlled "smart" charger with Deep Discharge and Recharge capabilities. It requires a 12VDC 0.75 Amp (Domestic) input from the power supply.

NOTE: Use only the power supply specified by Respironics.

Defective charger bases will be replaced at no charge during the warranty period. After the warranty period, if desired, the charger base may be repairable, however, attempts to remove the main PCB can cause permanent damage to the charger. To open and inspect/repair the charger base the following procedure must be followed. To reassemble, reverse the procedure.

- Gently remove the 4 clear plastic "feet" to expose the 4 assembly screws.
- Using a small tipped Philips screwdriver, remove the 4 screws.
- Gently separate the upper and lower case.
- Inspect the LED connections to ensure that they are securely connected.
- Connect the charger base to the power supply being careful not to short the PCB to tools etc. Note: Anti-Static protection is required to prevent possible damage to the micro-processor.
- Using the Schematic in Section 11.3.3 of this manual, a standard Digital Multi-meter, Oscilloscope, and small electronic service hand tools perform problem diagnosis and repair.
- Re-apply power to the charger base and place battery in well. Monitor BSI for correct indication (see section 12). Reassemble the charger base.
  The small spring-loaded battery contact pins in the charger base wells can be removed and replaced in the event they become bent or broken.

- Gently grasp the pin with a pair of small needle-nose pliers or equivalent and pull straight up. Once the pin is removed, a new pin can be inserted in the same manner. New pins (RI P/N 1014776) can be ordered from Respironics or your local distributor.

13.3 Hand-Held Unit (HHU) Repair

The Hand-Held unit (HHU) is not field-serviceable with the exception of the measurement light bulb. The unit must be returned to Respironics for service. If the HHU is opened, the accuracy of the instrument cannot be guaranteed and any remaining warranty will be voided.

13.4 Power Supply Repair/Replacement

The power supply has no serviceable components. In the event of failure, it must be replaced. If the failure occurs during the warranty period of the system, it will be replaced at no charge by Respironics. Out of warranty replacements can be purchased from Respironics or your local distributor.

13.5 Battery Pack Repair/Replacement

The Bili*Chek* battery pack contains 5 Ni-Cd batteries and is a sealed unit. Any attempt to open will destroy the pack. It is not repairable and will be exchanged at no charge during warranty. Out of warranty replacements may be purchased from Respironics or your local distributor.

NOTE: For diagnosis of suspected battery pack failure, see section 11.1 and section 11.3.1.

NOTE: Batteries must be disposed of properly and in accordance with local ordinance. Do not incinerate or throw in trash or land fills.

14.0 Software Upgrades

As software upgrades are required for system options or enhancements, instructions, software, and any required tools or equipment needed for the upgrade will be sent if requested.
NOTE: There may be a charge for software upgrades that are not required for product safety or effectiveness. Check with your local distributor for information regarding upgrades.

15.0 Respironics Customer Service and Product Support Contact Information

Respironics is committed to customer satisfaction and may be contacted with any questions or for technical support. For technical assistance contact Respironics Customer Satisfaction

US and Canada

Phone: 1-800-345-6443
Fax: 1-800-886-0245

International

Phone: 1-724-387-4000
Fax: 1-724-387-5012

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